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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,221

08/22/2006

Donald Darkin

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04/28/2009

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EXAMINER

BLIZZARD, CHRISTOPHER JAMES

ART UNIT

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3771

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,221	Applicant(s) DARKIN ET AL.	
	Examiner CHRISTOPHER BLIZZARD	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/12/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/12/2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/12/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to amendment filed of 5/12/2006. As directed by the amendment claims 3-8, 10, 12, 14, 19, 20, 22, 24 and 25 were amended, no claims were added. Thus, claims 1-26 are presently pending in this application.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "nozzle elements", "positioning structure", "alarm" and "detents" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 15, 16, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not disclose a way for an alarm to be sounded if the vent assembly is not in the first or second position.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13, 15, 16, 21, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claims 13 and 21, the trademarked term "GORE-TEX" renders the claim indefinite as it is unclear what is being limited by the term.

7. Regarding claims 15, 16, 25 and 26, the term "alarm" renders the claim indefinite as it is unclear what connection the "alarm" has to the claimed invention.

Claim Rejections - 35 USC § 103

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8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-7, 10, 11, and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon (6,662,803) in view of Wood (7,191,781).

10. Regarding claims 1-3, 5, 6, 10, 17, 18, 20 and 19 Gradon discloses a mask assembly comprising a frame that is a shell (102) with a cushion (104) and a vent assembly (300) comprising a first vent (308) with a noise reducing filter (column 4, line 66-67), and a second vent (310) of smaller size and less flow (column 5, lines 16-22). Gradon does not disclose a selector switch to switch the flow of exhaled gas from the patient between the first and second vents. Wood teaches a nasal assembly with a rotatable and pivotal selector switch (44) (fig. 10) to switch between a first (54) and a second (56) vent setting. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the mask assembly of Gradon with a selector switch as taught by Wood in order to provide the advantage of controlling the flow out of the mask assembly.

11. Regarding claims 4, 7, and 19, Gradon does not disclose a nozzle elements or a clip that is slidable with respect to the frame. Wood teaches nozzle elements (6) attached to a cushion (8) as well as a clip (64) that is slidable to select between first and second vents (fig. 16) (column 8, lines 11-14). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the mask

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assembly of Gradon with nozzle elements and a clip as taught by Wood in order to provide the advantages of providing a good seal with the patients nares and controlling the exhaust flow out of the mask assembly.

12. Regarding claims 11 and 21, Gradon disclosed the claimed invention except of the composition of the noise reducing material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the noise reducing material be chosen from a group of foam, and ceramic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

13. Claims 1, 8, 9, 12-14, 17, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon (6,662,803) in view of Bauman (4,821,713).

14. Regarding claims 1, 8, 9, 12, 13, 17, 22 and 23, Gradon discloses a mask assembly comprising a frame that is a shell (102) with a cushion (104) and a vent assembly (300) comprising a first vent (308) with a noise reducing filter (column 4, line 66-67), and a second vent (310) of smaller size and less flow (column 5, lines 16-22). Gradon does not disclose a selector switch to switch the flow of exhaled gas from the patient between the first and second vents located on a depending arm of an elbow. Bauman discloses a mask assembly with a selector switch (121) located on a dependant arm of an elbow (fig. 10) that has positioning structure to define positions (column 4, lines 62-65) that includes detents (121b, 122) to hold the switch in place (column 4, lines 66-68). Therefore it would have been obvious to one of ordinary skill in

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the art at the time the invention was made to provide the mask assembly of Gradon with a selector switch on an elbow as taught by Bauman in order to provide the advantages of controlling the air leaving the mask assembly from an easily accessible location.

15. Regarding claims 14 and 24, the combination of Gradon and Bauman is configured with a third vent position (Bauman, fig. 11), so it is configured for to vent exhaled gas even if the vent assembly is not in the first or second position.

16. Claims 15, 16, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gradon (6,662,803) and Bauman (4,821,713), as applied to claims 12 and 22 above, and further in view of Truschel (6,536,432).

17. Regarding claims 15, 16, 25, and 26, Gradon in combination with Bauman disclose the claimed invention except for an alarm. Truschel teaches a mask assembly that contains an alarm (48) that sounds when improper exhaust of gas is detected (Abstract), as such would be the case if vent was improperly aligned. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the mask assembly of Gradon and Bauman with an alarm as taught by Truschel in order to provide the advantage of a safety feature to prevent injury to the user.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Miser (4,919,132) a mask assembly with sliding vent covers, Stegmann (5,931,163) a exhaust valve with variable flow settings, Scrowski (6,615,830) a swivel elbow with exhaust ports, and Cise (6,629,530) a rotatable valve.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771